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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,196	12/04/2001	Keith D. Allen	R-632	6896

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EXAMINER	
BERTOGLIO, VALERIE E	
ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/005,196	Applicant(s) ALLEN ET AL.	
	Examiner Valerie E. Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a gene targeting construct and a method of producing the gene targeting construct, classified in class 536, subclass 23.1.

II. Claims 3-5, 8 and 22, drawn to a genetically modified animal cell, classified in class 435, subclass 325.

III. Claims 6,7,9 and 14-21, drawn to a non-human transgenic animal and methods of making the animal classified in class 800, subclass 21.

IV. Claims 10, 23, 29-32 drawn to methods of using a transgenic mouse with a disruption in the FPR-RS4 gene, classified in class 800, subclass 3.

V. Claims 11, 12 and 33, drawn to a method of identifying an agent by contacting the agent to a cell with a disruption in the FPR-RS4 gene, classified in class 530, subclass 350.

VI. Claims 13, 24 and 25, drawn to an agent that is an agonist to FPR-RS4, classified in class 530, subclass 350.

VII. Claims 13, 24 and 25, drawn to an agent that is an antagonist to FPR-RS4, classified in class 530, subclass 350.

VIII. Claim 26, drawn to an electronic database, classified in class 702, subclass 19.

IX. Claim 27 and 28, drawn to a method of treating anxiety, classified in various classes and subclasses.

X. Claim 34, drawn to a pharmaceutical composition containing FPR-RS4, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I relates to a DNA construct and a method for making the construct while invention II relates to a cell with a disruption in the FPR-RS4 gene. The construct does not depend on the cells and the cells can be made without the construct. The burden required to search inventions I and II together would be undue.

Inventions I and III are patentably distinct because the construct group I can be used to transfect cells in vitro while the mouse of invention III can be used as a model of disease. The construct of invention I does not have to be used to make the mouse of invention III, nor does the mouse of invention III require the construct of invention I. The burden required to search inventions I and III together would be undue.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the construct of invention I can be used to transfect cells in vitro while the method of invention IV can be used to identify agents that modulate FPR-RS4. The construct of invention I is not needed for the methods of invention IV and the method of invention IV is not required for the construct. The burden required to search inventions I and IV together would be undue.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention I can be used to express a protein while invention V can be used to identify an agent. The burden required to search inventions I and V together would be undue.

Invention I and inventions VI or VII are patentably distinct because the construct group I can be used to transfect cells in vitro while inventions VI and VII can be used to identify modulators of FPR-RS4. The burden required to search invention I and inventions VI and VII together would be undue.

Inventions I, III-V or IX and invention VIII are patentably distinct because the methods of inventions I, III-V and IX do not require the database of invention VIII and the database does not require the methods. The burden required to search inventions I, III-V and IX and invention VIII together would be undue.

Inventions I and IX are patentably distinct because the construct of invention I can be used to transfect cells in vitro while the methods of invention IX can be use as a method of treatment. The construct is not needed for the method and the method is not needed for the construct. The burden required to search invention I and IX together would be undue.

Inventions I and X are patentably distinct because the construct group I can be used as a probe while the pharmaceutical composition of invention X can be used to treat disease. The construct of invention I is not needed for invention X, nor is invention X needed for the construct. The burden required to search invention I and X together would be undue.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic animals and methods of making the animals of invention III do not necessarily require the cells of invention II and the cells can be used for distinctly different processes such as screening compounds. The burden required to search invention II and III together would be undue.

Inventions II and IV are patentably distinct because the cells of invention II can be used to screen compounds while the method of invention IV can be used as a model of disease. The cells of invention II is not needed for the methods of invention IV and the method of invention IV is not required for the cells. The burden required to search inventions II and IV together would be undue.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case agents that modulate FPR-RS4 expression or activity can be identified using transgenic animals or in vitro protein and DNA binding experiments while the cells of invention II can be used in differential expression assays. The burden required to search inventions II and V together would be undue.

Inventions II and inventions VI or VII are patentably distinct because the cells of group II can be used to make protein or test gene expression while the agents of invention VI and VII can be used to modulate FPR-RS4 gene expression or activity. The cells are not necessary for the

modulators nor are the modulators necessary for the cells. The burden required to search invention II and invention VI and VII together would be undue.

Inventions II and VIII are patentably distinct because the cells of invention II can be used to isolate protein while the database of invention VIII can be used for statistical analysis. The cells are not necessary for the database nor are the database necessary for the cells. The burden required to search invention II and VIII together would be undue.

Invention II and IX are patentably distinct because the cells of invention II can be used to identify FPR-RS4 modulators while the method of treating disease can be used to treat patients. The cells are not needed for the method and the method is not needed for the cells. The burden required to search invention II and IX together would be undue.

Inventions II, III, VI or VII and invention X are patentably because the cells of invention II, the transgenics of invention II, and the FPR-RS4 modulators of inventions VI and VII are not necessary for the pharmaceutical composition of invention X and the pharmaceutical composition is not needed for the products of inventions II< III, VI and VII. The burden required to search invention II, III, VI and VII and invention X together would be undue.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case agents can be identified using cells deficient of FPR-RS4 and the transgenic animals can be used for phenotypic analysis. The burden required to search inventions III and IV together would be undue.

Inventions III and V are patentably distinct because invention III can be used as a disease model while invention V can be used to identify an agent. The transgenic animals are not needed for the methods of using the cells and the methods are not needed for the transgenics. The burden required to search inventions III and V together would be undue.

Inventions III and inventions VI or VII are patentably distinct because invention III can be used as a disease model while invention VI and VII can be used to modulate FPR-RS4 activity. The transgenic animals are not needed for modulators and the modulators are not needed for the transgenics. The burden required to search invention III and inventions VI and VII together would be undue.

Inventions III and inventions IX are patentably distinct because the transgenics of invention III can be used to generate cell lines while the methods of invention IX are used to treat disease. The transgenics are not needed for the methods and the methods are not needed for the transgenics. The burden required to search inventions III and IX together would be undue.

Inventions IV and V are patentably distinct because the methods of invention IV are materially different from the methods of invention V. The methods of invention IV make use of transgenic animals while invention V uses cells. Invention IV is not needed for invention V and invention V is not needed for invention IV. The burden required to search inventions IV and V together would be undue.

Invention IV and inventions VI or VII are patentably distinct because the methods of invention IV can be used to identify modulators of FPR-RS4 while the agents of invention VI and VII can be used to modulate FPR-RS4 gene expression or activity in cells. The methods are

not necessary to make the agent nor are the agents necessary for the methods. The burden required to search invention IV and inventions VI and VII together would be undue.

Inventions IV and IX are patentably distinct because the methods of each invention are materially different and plurally independent from each other because they are practiced with materially different process steps, technical considerations, and reagents. The methods of invention IV are not needed for those of invention IX and the methods of invention IX are not needed for invention IV. The burden required to search inventions IV and IX together would be undue.

Inventions IV and X are patentably distinct because the methods of invention IV can be used to identify modulators of FPR-RS4 while invention X related to a pharmaceutical composition that can be used to treat disease. The method of invention IV is not necessary for the pharmaceutical of invention X and the pharmaceutical is not needed for the method.

Invention V and inventions VI or VII are patentably distinct because the methods of invention V can be used to identify modulators of FPR-RS4 while the agents of invention VI and VII can be used to modulate FPR-RS4 gene expression or activity in cells. The methods are not necessary to make the agent nor are the agents necessary for the methods. The burden required to search invention V and inventions VI and VII together would be undue.

Inventions V and IX are patentably distinct because the methods of each invention are materially different and plurally independent from each other because they are practiced with materially different process steps, technical considerations, and reagents. The methods of invention V are not needed for those of invention IX and the methods of invention IX are not

needed for invention V. The burden required to search inventions V and IX together would be undue.

Inventions V and X are patentably distinct because the methods of invention V can be used to identify modulators of FPR-RS4 while the pharmaceutical composition can be used to treat disease. The methods are not needed for the composition and the composition is not needed for the methods. The burden required to search inventions V and X together would be undue.

Inventions VI and VII are patentably distinct because each is directed to products that differ considerably in composition, structure and function. An agent of invention VI acts as an agonist in modulating FPR-RS4 while that of invention VII acts an antagonist of FPR-RS4. The burden required to search inventions VI and VII together would be undue.

Inventions VI or VII and invention VIII are patentably distinct because each is directed to products that differ considerably in composition, structure and function. The modulators of inventions VI and VII do not require the database of invention VIII and the database does not require the methods. The burden required to search inventions VI and VII and invention VIII together would be undue.

Inventions VI or VII and invention IX are patentably distinct because the agents of invention VI and VII can be used to modulate FPR-RS4 activity or expression while the methods of invention IX are used to treat disease. The agents are not needed for the method and the method is not needed for the agent. The burden required to search inventions VI and VII and invention IX together would be undue.

Inventions IX and X are related as product and process of use. In the instant case the protein of invention X can be used to make antibodies and the process of treating disease of

invention IX can be accomplished using materially distinct compounds. The burden required to search inventions IX and X together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL C. WILSON
PATENT EXAMINER